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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

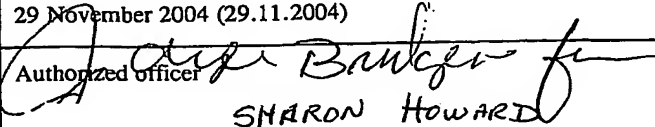
Applicant's or agent's file reference 15280-4742PC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/28889	International filing date (day/month/year) 12 September 2003 (12.09.2003)	Priority date (day/month/year) 12 September 2002 (12.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 9/14, 9/16, 31/33 and US Cl.: 424/489, 490; 514/183		
Applicant THE GOVERNMENT OF THE UNITED STATES, AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 09 April 2004 (09.04.2004)	Date of completion of this report 29 November 2004 (29.11.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  SHARON HOWARD Telephone No. (571) 272-1600

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/28889

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
 pages 1-19 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.
- ☒ the claims:
 pages 20-22 as originally filed
 pages NONE as amended (together with any statement) under Article 19
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.
- ☒ the drawings:
 pages 1-8 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/28889

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-30</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-30</u>	NO
Industrial Applicability (IA)	Claims <u>1-30</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-30 lack an inventive step under PCT Article 33(3) as being obvious over Morozov et al. (U.S. Patent No. 5,807,830).

Morozov teaches pharmaceutical compositions for intranasal administration for therapeutic treatment (see col. 26, lines 27-63). The reference teaches Mycobacterium tuberculosis (see col. 8, lines 5 and 6).

The reference does not particularly teach an average particle size.

However, absent a showing in the criticality of the particular particle size, there are no unexpected results. Thus, it would have been obvious to one of ordinary skill in the art to use the teachings of the Morozov reference, because the reference teaches a composition comprising capreomycin which is known in the pharmaceutical art to be administered intranasally. The expected result would be treating bacterial infections.

Claims 1-30 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

US 5,807,830 A (MOROZOV et al.) 15 September 1998.

PATENT COOPERATION TREATY

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/28889	Applicant's or agent's file reference 15280-4742PC	Date of informal communication (day/month/year) 15 November 2004 (15.11.2004)
Applicant THE GOVERNMENT OF THE UNITED STATES, AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<table style="width: 100%;"> <tr> <td style="width: 40%;"><u>Participants</u></td> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Identity checked</td> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 10%;">authorization checked</td> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 10%;">personally known</td> </tr> </table> <p><input checked="" type="checkbox"/> Applicant: THE GOVERNMENT OF THE UNITED STATES, AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND</p> <p><input type="checkbox"/> Agent:</p> <p><input checked="" type="checkbox"/> Examiner(s): Sharon Howard</p>	<u>Participants</u>	<input checked="" type="checkbox"/>	Identity checked	<input checked="" type="checkbox"/>	authorization checked	<input checked="" type="checkbox"/>	personally known
<u>Participants</u>	<input checked="" type="checkbox"/>	Identity checked	<input checked="" type="checkbox"/>	authorization checked	<input checked="" type="checkbox"/>	personally known		

Summary of communication:

The attorney informed the examiner to skip the PCT/IPEA 408 and to complete the PCT/IPEA/409.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer
 Sharon Howard

Telephone No. (571) 272-1600

PCT REQUEST

15280-4742PC

Original (for SUBMISSION) - printed on 12.09.2003 03:07:43 PM

VIII-4-1	Declaration: Inventorship (only for the purposes of the designation of the United States of America) Declaration of inventorship (Rules 4.17(iv) and 51bis.1(a)(iv)) for the purposes of the designation of the United States of America:	<p>I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.</p> <p>This declaration is directed to the international application of which it forms a part (if filing declaration with application).</p> <p>I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.</p> <p>I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.</p>
VIII-4-1 -1	Prior applications:	

PCT REQUEST

15280-4742PC

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		<p>I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.</p> <p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>
VIII-4-1 -1-1	Name:	KRAUS, Carl, N.
VIII-4-1 -1-2	Residence: (city and either US State, if applicable, or country)	Gaithersburg, Maryland
VIII-4-1 -1-3	Mailing address:	408 Ridgpoint Place
VIII-4-1 -1-4	Citizenship:	US
VIII-4-1 -1-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1 -1-6	Date: (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	

PCT REQUEST

15280-4742PC

Original (for SUBMISSION) - printed on 12.09.2003 03:07:43 PM

VIII-4-1 -2-1	Name:	BARRY, Clifton, E.
VIII-4-1 -2-2	Residence: (city and either US State, if applicable, or country)	Rockville, Maryland
VIII-4-1 -2-3	Mailing address:	200 Congressional Lane
VIII-4-1 -2-4	Citizenship:	US
VIII-4-1 -2-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1 -2-6	Date: (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	
VIII-4-1 -3-1	Name:	DOAN, Bernardan, T.
VIII-4-1 -3-2	Residence: (city and either US State, if applicable, or country)	Falls Church, Virginia
VIII-4-1 -3-3	Mailing address:	7757 Marshall Heights Court
VIII-4-1 -3-4	Citizenship:	US
VIII-4-1 -3-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1 -3-6	Date: (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	